Support for Amendments:

Amendments to claims 9, 11 and 12 are supported by the description on at least page 1, lines 7 to 9 and page 2, line 26 spanning to page 3, line 7.
Amendment to claim 13 is supported by the description on at least page 1, lines 7 to 9.
Amendment to claim 17 corrects a typographical error where the referenced claim was not to an apparatus. The claim to which claim 17 is now dependent is claim 13 rather than claim 12.

Remarks:

35 U.S.C. 102(b) Rejections

Claims 9, 13, 14, 15, and 17 were rejected as being anticipated by Gaster (US 2001/0019055, hereinafter Gaster '055), alleging that Gaster teaches the claimed process as evidenced at paragraphs 0017-0018 and figures 5-6.

Claims 9 and 13 were rejected as being anticipated by Bodenmann et al (USPN 4196565, hereinafter '565), alleging that Bodenmann et al taught the claimed process as evidenced at col 2, lines 41-51 and figures 1 to 5, further noting that a sealing clamp was inherent with the holding operation of Bodenmann et al.

Claims 9, 10, 13, and 14 were rejected as being anticipated by Lebrun et al (USPN 4940499, hereinafter Lebrun '499), alleging that Lebrun et al taught the claimed process as evidenced at the abstract; col 3, line 34 to col 4, line 5; col 5, lines 1 to 5; col 8, lines 26 to 52; and figures 1 to 13.

35 U.S.C. 103(a) Rejections

Claims 10 to 12 and 16 were rejected as being unpatentable over Gaster '055 for the reasons provided for the rejection based on 102(b). Regarding claims 10 to 12, it was further alleged that it is well-known in the molding art to clean a molded product after molding and a molding apparatus before the next molding cycle. Thus, it was alleged, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to clean the excess sealing fluid from the claimed locations in order to produce a high quality product

and to ensure a proper molding operation. Regarding claim 16, sealing clamps having airing and suction ports are well-known in the molding art as effective means for positioning and releasing a preform. Thus, it was alleged, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include airing and suction ports in the apparatus of '055 in order to enhance the positioning and releasing of the perform within the apparatus of '055.

Claims 11 to 12 and 15 to 17 were rejected as being unpatentable over '499 for the reasons provided for the rejection based on 102(b). Regarding claims 11 to 12, it was further alleged that it is well-known in the molding art to clean a molded product after molding and a molding apparatus before the next molding cycle. Thus, it was alleged, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to clean the excess sealing fluid from the claimed locations in order to produce a high quality product and to ensure a proper molding operation. Regarding the liquid recovery grooves, it was further alleged that such are well-known in the molding art in order to reduce manufacturing costs. Therefore, it was alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include liquid recovery grooves in the apparatus of '499 in order to reduce manufacturing costs. Regarding claim 16, sealing clamps having airing and suction ports are well-known in the molding art as effective means for positioning and releasing a perform. Thus, it was alleged, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include airing and suction ports in the apparatus of '499 in order to enhance the positioning and releasing of the perform within the apparatus of '499.

Arguments:

Applicant respectfully traverses all rejections. The rejections will be addressed in the order in which they were presented in the non-final Office Action. However, Applicant first reiterates the key aspects of the present invention to facilitate responding to the various rejections. The present invention concerns a method for the sealing of hard shell capsules having coaxial body parts which overlap when telescopically joined. Also described is an apparatus to seal the capsules. The method comprises the steps of holding the capsule in a

precise and upright position and injecting a quantity of sealing fluid in the overlap of the body parts. An apparatus for performing the method is also disclosed. The apparatus comprises a sealing clamp to hold the capsule in an upright position and means to inject the sealing fluid in the overlap of the body parts. The capsules may be made of gelatin or of other materials whose properties are pharmaceutically acceptable with respect to their chemical and physical properties. See, e.g., Abstract and page 1, lines 5 to 9.

102(b) Rejections

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1063 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) (claim to a system for setting a computer clock to an offset time to address the Year 2000 (Y2K) problem, applicable to records with year date data in "at least one of two-digit, three-digit, or four-digit" representations, was held anticipated by a system that offsets year dates in only two-digit formats). See also MPEP2131.02 "The identical invention must be shown in as complete detail as is contained in the claim." *Richland v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1931, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Note that, in some circumstances, it is permissible to use multiple references in a 35 U.S.C. 102 rejection. See MPEP § 2131.01. [MPEP 2131.]

Gaster '055:

The process in Gaster '055 utilizes a thermosetting plastic material to form an **over-molded** section. The liquid plastic material is introduced into a mold which is positioned around **abutting and adjacent** portions of the components. The mold comprises of upper and lower mold members 11 and 12. "As shown in FIG. 3, the mold members are clamped together by any suitable means so that the inner surfaces 26 and 27 of the flanges are abutting." [0017], page 2, lines 3 to 5. See generally, [0003], [0016] and [0017], emphasis added. Although the mold members are clamped, there is no clamping of any component members where said component members are abutting when ultimately joined to create container 15. The way in which the mold members are clamped is not described. See [0017], page 2, line 4. Therefore, the disclosure as a whole of Gaster '055 does not anticipate the pending invention.

In the pending application, the components being sealed are held by a sealing clamp and the overlapping components are sealed while being held by said clamp. Two parts of a pharmaceutically acceptable capsule are **telescopically joined with coaxial partly overlapping** body parts and the sealing fluid is injected in the **overlap** of the telescopically joined parts. See, e.g., page 1, lines 7 to 9 and page 2, line 26 spanning to page 3, line 7. The present invention concerns sealing clamps used to hold each capsule and means to inject a quantity of sealing fluid into the overlapping body parts from the outside of telescopically joined with coaxial partly overlapping body parts.

Gaster '055 does not anticipate all of the claim limitations of the pending application concerning the method for holding and sealing and the apparatus to hold and means to seal the coaxial partly overlapping body parts of a capsule made of pharmaceutically acceptable material. Applicant, therefore, respectfully requests the withdrawal of the 102(b) rejection with regard to Gaster '055. If the rejection is not withdrawn, to the extent that the Examiner relies on his personal knowledge for the basis of the 102(b) rejection, Applicants request an affidavit. 37 C.F.R. 1.104(d)(2).

Bodenmann, '565

The invention in '565 relates to a method of producing a joined capsule filled with viscous material, in particular a liquid pharmaceutical preparation, and having a body part and a cap telescoped thereon the ridge of the body part received in the cap being sealed with respect to the adjacent area of the **inner side of the cap through an aperture** in the joined capsule, with a pasty solidifying sealing composition being inert with respect to the viscous material, in which the joined capsule is filled with the viscous material through the aperture. See, e.g., Abstract, Col 1, lines 34-35, and 43-46. For the composition to be applied to the inside of the cap, rotation about axis a-a must occur: A hollow needle 26 bent at its end is introduced into the aperture 18 in such a manner that an outlet opening 27 of the hollow needle 26 is closely adjacent to the inner side of the cap 8, in the area of the ridge 12 of the body part 10. The joined capsule which is oriented approximately vertically while the aperture 18 points in upward direction, is then slowly rotated about its own axis a-a, and from the outlet opening 27 of the hollow needle 26 of a strand 31 of the pasty sealing composition is extruded which is deposited on the transition area between ridge 12 and the inner side of

the cap 8. See col. 2, lines 41-51, and Fig 1, 4-5. Sealing the aperture is the last step. Claim 1.

Therefore, in '565, there are two sealing steps. First, the inner side of the cap is sealed by introducing a hollow needled through the aperture, slowly rotating about axis a-a, and then sealing the aperture. Unlike '565, there is one sealing process, that of applying the sealing fluid to the overlap of the body parts. See, e.g., page 3, lines 8 to 12. Furthermore, sealing clamps hold each capsule and there are means to inject a quantity of sealing fluid into the overlapping body parts from the outside of telescopically joined with coaxial partly overlapping body parts (see, e.g., page 3, lines 2-5), rather than the inside of the capsule as in '565. Hence, the process to make the sealed capsules in '565 does not anticipate the pending application.

It is also alleged that there is a "holding process" but said holding process is inherent:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.
>
> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic <u>necessarily</u> flows from the teachings of the applied

> prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.). [MPEP, 2112, IV.]

The office action provided no objective evidence and no cogent technical reasoning to support the allegation of a clamp being inherent in '565. It is Applicant's position that a clamp is not supported by the disclosure in '565. For example, the rotation required to apply the pasty sealing composition at the inner side of the cap would indicate a clamp is not necessarily used. Furthermore, an example of a manner to hold the capsule without clamping is given in Lebrun '499. See e.g., Lebrun '499, col 3, lines 48 to 50, in which it is described that a passageway blocking element holds each capsule against further movement while metered amounts of a wetting fluid are ejected from needle discharge outlets against the side wall of the body of the capsule. See also, col 8, lines 32 to 36, discussing Figures 3 and 10.

The invention in '565 does not anticipate the pending application. '565 fails to disclose the sealing process and apparatus of the pending application. The present invention concerns sealing clamps used to hold each capsule and means to inject a quantity of sealing fluid into the overlapping body parts from the outside of telescopically joined with coaxial partly overlapping body parts. Such a process and apparatus do not exist in '565, explicitly or inherently. Hence, Applicant respectfully requests the withdrawal of the 102(b) rejection based on '565. If the rejection is not withdrawn, Applicant requests objective evidence and/or cogent technical reasoning to support the allegation of a clamp being inherent in '565. If the rejection is not withdrawn, to the extent that the Examiner relies on his personal knowledge for the basis of the 102(b) rejection, Applicants request an affidavit. 37 C.F.R. 1.104(d)(2).

Lebrun '499:

Lebrun '499 discloses a method and an apparatus for sealing hard shell capsules. According to Lebrun '499, with reference, for example, to Figure 10, a capsule is fed into a capsule wetting section 20 through a corresponding passageway 68 and is stopped by engagement with the peripheral surface of a rotary dryer 22. See col. 8, lines 32 to 36. There is no clamp, of any kind, disclosed. Lebrun '499 fails to disclose the sealing process and apparatus of the pending application. The present invention concerns sealing clamps used to hold each capsule and means to inject a quantity of sealing fluid into the overlapping body parts from the outside of telescopically joined with coaxial partly overlapping body parts. The means to inject the sealing fluid can be integrated into the sealing clamp that also holds the capsule. Due to the clamping of the capsule by the sealing clamps, the sealing fluid is applied to a very specific area of the held capsule. Applicant respectfully requests the withdrawal of the 102(b) rejection based on Lebrun '499. If the rejection is not withdrawn, to the extent that the Examiner relies on his personal knowledge for the basis of the 102(b) rejection, Applicants request an affidavit. 37 C.F.R. 1.104(d)(2).

103(a) Rejections

Since the mailing of the pending Office Action, the Supreme Court issued its opinion in *KSR Int'l Co. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 1997). The USPTO has issued a Memorandum dated May 3, 2007. The Memorandum makes the following points:

> (1) The Court reaffirmed the *Graham* factors in the determination of obviousness under 35 U.S.C. 103(a). [Factors and citation omitted.]
>
> (2) The Court did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. 103(a)
>
> (3) The court rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

(4) The Court noted that the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. The Court specifically stated:

> Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

KSR, slip op. at 14 (emphasis in original).

Therefore, in formulating a rejection under 35 U.S.C. 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. [Emphasis in original.]

Gaster, '055:

It is Applicant's position that Gaster '055 is non-analogous art. Gaster '055 concerns the product and method of containers for waste material for industrial uses. [0003].

The MPEP states at 2141.01(a), Section I:

> The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

Applicant incorporates herein all arguments provided *supra* when responding to the 102(b) rejection based on Gaster '055. Applicant further directs attention to the following passage discussing the advantage of the subject matter in Gaster '055 to support the contention that Gaster '055 is nonanalogous art:

> The process permits the formation of the over-molded sections in a large range of profile configurations and cross-sections, whether thick or thin. The components to be sealed may be made of plastic materials, composites or metals. A mechanical or physical interface is provided between the components and the over-molding material. The use of these liquid thermosetting plastic materials avoids problems which could exist if conventional injection molding were to be used, wherein it is necessary to melt solid plastic granules at temperatures between 400 and 600 degrees

> Fahrenheit, and then forcing the melt into mold cavities at pressures that normally run between 12,000 and 16,000 PSi. In such a process, the components to be joined would be seriously degraded. In this process, there is no chemical reaction, and thus a corresponding absence of chemical degradation of the components which would otherwise occur if the process involved molding at high temperatures and/or pressures. In addition, there is no loss of physical integrity, or degradation, such as would occur if high temperatures were involved, which would cause melting and re-solidifying of the components. The process can be utilized for such products as hazardous waste containers, high or low pressure protective containers, pressure vessels, drums, pipe joints, fastening systems, fascia, and the like. [[0003].]

Furthermore, Gaster '055 concerns a typical container 15. The container as shown is metal, but could be made of a plastic material, such as polyvinyl chloride or polyethylene, or a fiber-reinforced composite. Gaster '055 does not disclose sealing clamps used to hold each capsule, composed of pharmaceutically acceptable material, and means to inject a quantity of sealing fluid into the overlapping body parts from the outside. Because of the subject matter of Gaster '055, this reference should be found to be non-analogous art.

Assuming, *arguendo*, that Gaster '055 has some relevance, and this is in no way agreeing to its relevance, as the May 3, 2007 Memorandum stated, the reasons must be made explicit to support a 103(a) rejection. Care must be taken to avoid the inappropriate use of hindsight to use Applicant's disclosure as a template for piecing together the alleged prior art. It is Applicant's position that the burden has not been shifted to require any further response. For example, there has been no analysis under *Graham*.

Applicants respectfully request the withdrawal of the 103(a) rejection for the pending claims. If the rejection is not withdrawn, to the extent that the Examiner relies on his personal knowledge for the basis of the 103 rejection, Applicants request an affidavit. 37 C.F.R. 1.104(d)(2). Moreover, if the rejection is not withdrawn, Applicant requests specific citations to the "well-known" technology referenced in the rejection to allow Applicant an opportunity to review any references.

Lebrun '499:

Applicant incorporates herein all arguments provided *supra* when responding to the 102(b) rejection based on Lebrun '499. Lebrun '499 does not use a clamp. See, e.g., col. 8, lines 32 to 36. Furthermore, Lebrun '499 does not disclose sealing clamps used to hold each capsule and means to inject a quantity of sealing fluid into the overlapping body parts from

the outside and one of ordinary skill in the art would not arrive at Applicant's invention from Lebrun '499. As the May 3, 2007 Memorandum stated, the reasons must be made explicit to support a 103(a) rejection. Care must be taken to avoid the inappropriate use of hindsight to use Applicant's disclosure as a template for piecing together the alleged prior art. It is Applicant's position that the burden has not been shifted to require any further response. For example, there has been no analysis under *Graham*.

Applicants respectfully request the withdrawal of the 103(a) rejection for the pending claims. If the rejection is not withdrawn, to the extent that the Examiner relies on his personal knowledge for the basis of the 103 rejection, Applicants request an affidavit. 37 C.F.R. 1.104(d)(2). Moreover, if the rejection is not withdrawn, Applicant requests specific citation to the "well-known" technology referenced in the rejection to allow Applicant an opportunity to review any references .

Supplemental IDS

The references contained in this Supplemental Information Disclosure Statement were cited in international search report. A review of the documents cited in this pending application resulted in the discovery that these references have not yet been provided in an IDS. The international search report was mailed on August 23, 2004. Please see the attached documents.

Conclusion

Applicant believes that the claims are in order for allowance, early notice of which is requested. If Examiner has any questions concerning this application, Examiner is invited to contact the below-signed attorney. A fee is due. Please charge any payment or credit any overpayment to Charge Account 16-1445.

Respectfully submitted,

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